

**IN THE UNITED STATES DISTRICT COURT  
EASTERN DISTRICT OF ARKANSAS  
WESTERN DIVISION**

<b>In re:</b>	<b>:</b>	<b>MDL Docket No. 4:03CV1507-WRW</b>
	<b>:</b>	<b>4:05CV00497</b>
<b>PREMPRO PRODUCTS LIABILITY</b>	<b>:</b>	
<b>LITIGATION</b>	<b>:</b>	
	<b>:</b>	
	<b>:</b>	
<b>HELENE RUSH</b>	<b>:</b>	<b>PLAINTIFF</b>
	<b>:</b>	
<b>v.</b>	<b>:</b>	
	<b>:</b>	
<b>WYETH</b>	<b>:</b>	<b>DEFENDANT</b>

**ORDER**

Pending are several *Daubert* motions: Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation (Doc. No. 136); Defendant's Motion to Exclude Expert Testimony of Dr. Hollon (Doc. No. 140); Defendant's Motion to Exclude Testimony of Dr. Guerigian (Doc. No. 142); Defendant's Motion to Exclude Expert Testimony of Dr. Sackett (Doc. No. 144); and Defendant's Motion to Exclude Expert Testimony of Dr. Austin (Doc. No. 148).<sup>1</sup> Also pending are Plaintiff's Motion to Preclude Defendant's Experts from Testifying That There is No Reliable Scientific Evidence that Combination Hormone Therapy Can Cause Breast Cancer (Doc. No. 193)<sup>2</sup> and Defendant's Motion for Summary Judgment Re: Specific Causation (Doc. No. 87).<sup>3</sup> Oral argument was heard on July 13-14, 2006 and again on July 31, 2006.

---

<sup>1</sup>Plaintiff has responded to each motion (Doc. Nos. 211, 215, 213, 203).

<sup>2</sup>Defendant has responded (Doc. No. 225).

<sup>3</sup>Plaintiff has responded (Doc. No. 111) and Defendant has replied (Doc. No. 175).

## **I. STANDARD**

### **A. Burden of Proof**

The admission of expert testimony is governed by Rule 702 of the Federal Rules of Evidence, which reads:

If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.<sup>4</sup>

When a party proffers an expert witness, deciding whether Rule 702 is satisfied is a preliminary issue governed by Federal Rule of Evidence 104(a).<sup>5</sup> Rule 104(a) requires the proponent of evidence to establish its admissibility by a preponderance of the evidence.<sup>6</sup> In determining admissibility, the court is not bound by any of the rules of evidence, except with regard to privilege.<sup>7</sup>

### **B. Legal Standard for Admissibility**

The central inquiry under Rule 702 is whether the proffered expert's testimony is sufficiently reliable.<sup>8</sup> The trial court serves a gatekeeping function, ensuring that any expert testimony is reliable and relevant.<sup>9</sup>

---

<sup>4</sup> Fed. R. Evid. 702.

<sup>5</sup> *U.S. v. Martinez*, 3 F.3d 1191, 1196 n.10 (8th Cir. 1993).

<sup>6</sup> *Bourjaily v. U.S.*, 483 U.S. 171 (1987).

<sup>7</sup> Fed. R. Evid. 104(a).

<sup>8</sup> *First Nat'l Bank v. Benham*, 423 F.3d 855, 861 (8th Cir. 2005).

<sup>9</sup> *Id.*

To be admissible, expert testimony must satisfy the two prongs of Rule 702.<sup>10</sup> First, it must be based on scientific, technical, or other specialized knowledge.<sup>11</sup> If the testimony is scientific, it must be grounded in the methods and procedures of science.<sup>12</sup> Likewise, “knowledge” requires more than a subjective belief or an unsupported speculation, requiring instead an appropriate level of validation.<sup>13</sup> Second, the testimony must be relevant, in that it must help the trier of fact either understand the evidence or determine a fact in issue.<sup>14</sup> The burden of establishing relevancy and reliability rests on the proponent of the expert testimony.<sup>15</sup>

Courts have used a variety of factors to determine the reliability of proffered expert testimony. The most frequently discussed factors are those derived from the Supreme Court’s opinion in *Daubert*, where the Court established that the trial court may consider:

(1) whether the theory or technique can be or has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) whether the theory or technique has a known or potential error rate and standards controlling the technique’s operation; and (4) whether the theory or technique is generally accepted in the scientific community.<sup>16</sup>

Because the inquiry is “flexible and fact-specific, a court should use, adapt, or reject *Daubert* factors” as needed based on the facts of a particular case.<sup>17</sup>

---

<sup>10</sup>*U.S. v. Cawthorn*, 429 F.3d 793, 799 (8th Cir. 2005).

<sup>11</sup>*Id.*

<sup>12</sup>*Id.*

<sup>13</sup>*Id.* at 799-800 (quoting *Daubert v. Merrell Dow Pharm.*, 509 U.S. 579, 590 (1993)).

<sup>14</sup>*Id.* at 799.

<sup>15</sup>*Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278-78 (5th Cir. 1998).

<sup>16</sup>*Benham*, 423 F.3d at 861 (citing *Daubert*, 509 U.S. at 593-94).

<sup>17</sup>*Unrein v. Timesavers, Inc.*, 394 F.3d 1008, 1011 (8th Cir. 2005).

The most recent amendments to Rule 702 added three general standards for courts to use in determining the reliability and relevance of proffered expert testimony. First, the proffered testimony must be based on sufficient facts or data.<sup>18</sup> Second, it must be the product of reliable principles and methods.<sup>19</sup> Third, the expert must have applied those principles and methods reliably to the facts of the case.<sup>20</sup>

The focus is not on the expert's conclusion, but on the methodology.<sup>21</sup> The proponent of the testimony "need not prove . . . that the expert's testimony is correct, but . . . must prove by a preponderance of the evidence that the testimony is reliable."<sup>22</sup> Determining the validity of an expert's conclusions is the duty of the finder of fact.

## II. ANALYSIS

### A. Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation (Doc. No. 136)

Drs. Suzanne Klimberg and James A. Waldron were retained by Plaintiff to testify on both the general and specific causation of Plaintiff's breast cancer.

Defendant asserts several reasons for excluding the expert testimony of Drs. Klimberg and Waldron: (1) the opinions were created exclusively for this litigation; (2) the opinions are not based on sufficient facts or data;<sup>23</sup> (3) differential diagnosis is not reliable to determine the

---

<sup>18</sup>Fed. R. Evid. 702(1).

<sup>19</sup>Fed. R. Evid. 702(2).

<sup>20</sup>Fed. R. Evid. 702(3).

<sup>21</sup>*Moore*, 151 F.3d at 275-76.

<sup>22</sup>*Id* at 276.

<sup>23</sup>Specifically Defendant claims that the opinions lack support because: (1) scientists do not know what causes breast cancer in an individual woman; (2) there is no test to identify the

cause of breast cancer; (4) and the “Gail Model” is not reliable to determine the cause of breast cancer.<sup>24</sup> Defendant also contends that Drs. Klimberg and Waldron are not qualified to testify because Dr. Klimberg has “never published -- or even presented -- the opinions regarding the cause of breast cancer” and Dr. Waldron’s “previous experience with breast cancer was limited to analyzing breast biopsies and determining whether the tissue was cancerous, not identifying the cause of cancer.”<sup>25</sup>

Plaintiff counters that Drs. Klimberg’s and Waldron’s opinions are based on scientifically reliable evidence. Additionally, Plaintiff claims that as a surgical oncologist and director of the breast cancer program at the Arkansas Cancer Research Center at UAMS<sup>26</sup> (Dr. Klimberg) and a diagnostic surgical pathologist and professor of pathology at UAMS (Dr. Waldron), both experts are qualified to testify as experts regarding causation.

Defendant’s attacks on Drs. Klimberg’s and Waldron’s qualifications do not pass muster. Both experts have experience and understanding regarding breast cancer and their opinions are bottomed upon scientifically reliable information.

In formulating their opinions, Drs. Klimberg and Waldron relied on their training, knowledge, and experience as a surgical oncologist and pathologist, respectively. They reviewed and relied on numerous published, peer-reviewed medical literature and studies. While

---

cause of breast cancer; (3) there is no physical characteristic that distinguishes breast cancers based on their cause; and (4) there is no way to separate the effect of naturally-occurring hormones and hormone therapy. *See* Doc. No. 137.

<sup>24</sup>Doc. No. 137.

<sup>25</sup>Doc. No. 137.

<sup>26</sup>University of Arkansas for Medical Sciences.

both reports are primarily conclusive, rather than explanatory, I don't believe that either expert used improper methodology. Dr. Klimberg's report on general causation reads:

To make a causal assessment in an individual case, one would need to consider the totality of evidence, including statistical association, details about generally recognized and statistically significant risk factors, physiological response to the drugs, such as radiological evidence of changes in breast density before, during, and after hormone therapy use, pathological biomarkers in the breast tissue samples during biopsy and surgery, as well as duration of use of the hormone therapy drugs.<sup>27</sup>

Defendant faults the experts for using differential analysis. However, reliance on differential analysis is not fatal when epidemiological studies also support the expert's conclusions.<sup>28</sup> Raising significant questions about the experts' analysis and conclusions is something Defendant can do for the jury.

Also, Defendant claims that, since scientists don't know what causes breast cancer, Plaintiff's experts cannot opine that Plaintiff's breast cancer was caused by HRT. Defendant's focus is too narrow. Plaintiff's experts need not conclude that HRT definitively caused Plaintiff's cancer; they must only establish that it was more likely than not a cause -- or that it promoted her cancer. That said, Plaintiff's experts' conclusions that HRT was "a substantial contributing factor"<sup>29</sup> in the development or promotion of Plaintiff's breast cancer chins the pole.

Again, while both reports are somewhat conclusive, rather than explanatory, I cannot say that either expert used improper methodology. In sum, both experts are qualified to testify that

---

<sup>27</sup>Doc. No. 157, Ex. 20.

<sup>28</sup>See *Ambrosini v. Labarraque*, 101 F.3d 129, 140-41 (D.C. Cir. 1996) (holding that expert testimony which relied, in part, on a differential analysis ruling out alternative sources of plaintiff's injury, was admissible, where epidemiological studies also indicated causal nexus).

<sup>29</sup>Doc. No. 157, Exs. 21, 29.

HRT more likely than not caused or promoted Plaintiff's breast cancer. Their conclusions can be tested during cross-examination.

**B. Defendant's Motion to Exclude the Expert Testimony of Dr. Austin (Doc. No. 148)**

Dr. Donald Austin will testify that, with proper monitoring, Wyeth could have and should have detected a signal in the 1980s that HRT may have been causing a disproportionate increase in certain types of breast cancer. Dr. Austin focused his report on "whether routine monitoring of breast cancer incidence from a publicly available source of such data of [sic] could have identified an anomalous increase in the incidence of invasive lobular carcinoma ["ILC"] in the U.S. during the period 1980-2000."<sup>30</sup>

Defendant contends that Dr. Austin's expert testimony should be excluded because: (1) it is unreliable since it was "developed solely for litigation," has not been tested, and has not been peer-reviewed or published;<sup>31</sup> (2) it does not "fit"<sup>32</sup> in the facts of this case because Ms. Rush did not have ILC; (3) none of Dr. Austin's findings can be used as evidence that HRT increased the risk of breast cancer of any type; and (4) there is no evidence that information about increased risk of particular breast cancer cell types would have affected a physician's decisions to prescribe HRT.<sup>33</sup>

---

<sup>30</sup>Doc. No. 157, Ex. 1.

<sup>31</sup>Doc. No. 149.

<sup>32</sup>See *Concord Boat Corp. v. Brunswick Corp.*, 207 F.3d 1039, 1055 (8th Cir. 2000) (recognizing that "[i]n recent years the Supreme Court has put renewed emphasis on the importance of the 'fit' of an expert's opinion to the data or facts in the case").

<sup>33</sup>Doc. No. 149.

**1. Unreliable** -- Wyeth's arguments on this point are standard *Daubert* challenges. However, these challenges are insufficient, even when considered cumulatively. First, "the fact of publication (or lack thereof) in a peer reviewed journal [is] . . . a relevant, though not dispositive, consideration."<sup>34</sup> Second, the fact that this research was conducted solely for this litigation, while noteworthy, is not fatal. When an expert develops opinions "expressly for the purposes of testifying," the proponent is required to "come forward with other objective, verifiable evidence that the testimony is based on 'scientifically valid principles.'"<sup>35</sup> Here, Dr. Austin's objective evidence is the SEER database he reviewed when compiling the data regarding the number of breast cancer incidences. As far as I can tell, Dr. Austin researched the database looking for a trend and reported the information that he discovered. Additionally, I don't find anything scientifically infirm about compiling data. It appears to me that the conclusions he makes are based on a review of the objective evidence in the database.

**2. "Fit"**-- Defendant also contends that Dr. Austin's findings are not relevant to this case because Plaintiff was diagnosed with ductal breast cancer, and Dr. Austin's findings refer to lobular breast cancer. Specifically, Dr. Austin concludes that his findings "represent a real and statistically significant increase in the proportions of ILC and Mixed Ductal/Lobular cancer relative to all invasive breast carcinoma."<sup>36</sup> Relying on Dr. Austin's report, Plaintiff contends that had Wyeth been keeping track of the information in the SEER database, it would have noticed "a surge in lobular breast cancer that mirrored the rise in the sale of E+P."<sup>37</sup>

---

<sup>34</sup>*Daubert*, 509 U.S. at 593.

<sup>35</sup>*Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311, 1317-18 (9th Cir. 1995) (quoting *Daubert*, 509 U.S. at 597).

<sup>36</sup>Doc. No. 157, Ex. 2.

<sup>37</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), Doc. No. 266.

Plaintiff further contends that this “knowledge would have caused a reasonably prudent manufacturer to conduct further studies on all hormone positive breast cancers,” probably resulting in the issuance of an adequate label before Plaintiff’s ductal cancer was caused or promoted.<sup>38</sup>

While I have some doubt about Dr. Austin’s analysis, “doubts regarding whether an expert’s testimony will be useful should generally be resolved in favor of admissibility.”<sup>39</sup>

**3. Causation** -- Plaintiff and Dr. Austin both concede that he could not comment on causation.<sup>40</sup> Accordingly, Dr. Austin will not be permitted to testify regarding causation.

**4. Irrelevant to Prescribing Decision** -- Defendant also contends that Dr. Austin’s testimony is irrelevant because “there is no evidence that information about risk of particular breast cancer cell types -- as opposed to the overall risk of breast cancer -- would matter to doctors in prescribing hormone therapy.”<sup>41</sup> Since Plaintiff is presenting Dr. Austin’s testimony to establish “what *defendants* should have done with the information, not what physicians would have done,”<sup>42</sup> Defendant is off the mark. Plaintiff’s position is well-taken.

**C. Defendant’s Motion to Exclude the Expert Testimony of Dr. Hollon (Doc. No. 140).**

Dr. Matthew Hollon plans to testify that Wyeth failed to meet the reasonable standard for care for drug promotion. He contends that Wyeth used promotional techniques irresponsibly and

---

<sup>38</sup>*Id.*

<sup>39</sup>*Clark by and through Clark v. Heidrick*, 150 F.3d 912, 915 (8th Cir. 1998).

<sup>40</sup>Doc. No. 157, Ex. 1 and Doc. No. 285.

<sup>41</sup>Doc. No. 232.

<sup>42</sup>Doc. No. 203 (emphasis in original).

excessively, which directly influence physicians' prescribing practices.<sup>43</sup> Plaintiff asserts that Dr. Hollon should be permitted to testify that "Wyeth engaged in longstanding manipulation of conventional wisdom on hormone therapy . . . [and] that physicians are influenced by marketing, notwithstanding their denials."<sup>44</sup>

Dr. Hollon is a practicing physician in internal medicine, with a Masters in Public Health, who has published several articles on pharmaceutical advertising.<sup>45</sup> He also teaches at the University of Washington in Seattle, and "has conducted independent social science research and written evidenced-based reviews and editorials" on pharmaceutical marketing.<sup>46</sup>

Defendant points out that although Dr. Hollon has published several pieces on pharmaceutical advertising, they were all editorials.<sup>47</sup> As stated above, Wyeth contends that Dr. Hollon should be prevented from testifying because his positions are not scientific, but personal opinions. Dr. Hollon's testimony need not be scientific. Rule 702 permits a witness to testify in the form of an opinion when that expert possesses scientific, technical, or other specialized knowledge that will assist the trier of fact. Clearly, Dr. Hollon has a knowledge of pharmaceutical marketing that is beyond a juror's common understanding. Although Defendant challenges the basis for his opinions, such challenges are issues for cross-examination.

However, Dr. Hollon's testimony about Wyeth's marketing will be limited to the issues in this case. For example, Plaintiff's position that "Dr. Hollon's expertise transcends the

---

<sup>43</sup>Doc. No. 157, Ex. 16.

<sup>44</sup>Doc. No. 209.

<sup>45</sup>Doc. No. 157, Ex. 16.

<sup>46</sup>Doc. No. 209.

<sup>47</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), July 31, 2006, Tr. at 141-142.

individual transaction to examine the general influence of promotional activities that violate public health principles" and "that given the extent of the promotional campaign, [Wyeth] certainly had undue influence on prescribing practices within this country" is too broad.<sup>48</sup> The United States Supreme Court has held that, even at the punitive damages stage of a trial, evidence of tortious conduct "must have a nexus to the specific harm suffered by the plaintiff . . . A defendant should be punished for the conduct that harmed the plaintiff, not for being an unsavory individual or business."<sup>49</sup>

It seems to me that any evidence of Defendant's "badness" during the punitive damage portion of the trial (if there is one) must be connected to Ms. Rush's injury. However, the nexus between Plaintiff and the advertisements need not be as strong as the causation requirements during the liability stage of the trial.<sup>50</sup> Dr. Hollon can testify regarding advertisements -- however, those advertisements must pertain to issues that are directly linked to Plaintiff, e.g. cardiac benefit, breast cancer, etc. Dr. Hollon will not be permitted to testify regarding general badness or badness in the specific areas which is not connected to Ms. Rush's injury.

#### **D. Defendant's Motion to Exclude the Expert Testimony of Dr. John Gueriguiian (Doc. No. 142)**

In a July 24, 2006 letter, I requested that Plaintiff submit, as she suggested in the July 13-14, 2006 hearing, a short summary of Dr. Gueriguiian's testimony.<sup>51</sup> In her July 27,

---

<sup>48</sup>Doc. No. 141.

<sup>49</sup>*State Farm Mutual Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 422-23 (2003).

<sup>50</sup>I previously held that Plaintiff would not be permitted to discuss advertisements that neither she nor her physician saw. However, at the punitive damages stage, the "nexus" can be a bit more attenuated.

<sup>51</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), Doc. No. 280.

2006 response letter, Plaintiff asserted that Dr. Gueriguian would present testimony regarding: (1) the United States Food and Drug Administration's ("FDA") role and authority; (2) the use and purpose of labels/warnings in communicating risk information to physicians and patients; (3) the history of Wyeth's HRT drugs; (4) breast cancer signals and Wyeth's failure to test for a connection between breast cancer and HRT; (5) purported cardiac and cognitive benefits of HRT and Wyeth's failure to test for such benefits; (6) assessment of the risks and benefits of a prescription drug; and (7) the differences between "estrogen alone, Old E+P, and New Prempro."<sup>52</sup> In sum, Dr. Gueriguian will testify about the history of the development of HRT and that Wyeth had a duty to WHI-type randomized controlled trial in 1980s, because that is what a reasonably prudent pharmaceutical company would do.<sup>53</sup>

Wyeth contends that Dr. Gueriguian's testimony should be excluded because: (1) his opinions will not assist the jury; (2) he lacks expertise to testify about Wyeth's marketing practices or FDA's review of promotional pieces; (3) he knows nothing about this specific case; and (4) he does not employ a reliable methodology.<sup>54</sup>

Dr. Gueriguian is a physician with specialty training in internal medicine, endocrinology, and pharmacology.<sup>55</sup> From 1978 to 1998 he worked at the FDA in the Division of Endocrine and Metabolic Drug Products. While at the FDA, Dr. Gueriguian reviewed drugs for safety and

---

<sup>52</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), Doc. No. 289. *See also* Doc. No. 215.

<sup>53</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), July 13, 2006, Tr. at 130.

<sup>54</sup>Doc. No. 143.

<sup>55</sup>Doc. No. 215.

efficacy; applied FDA regulations regarding labeling, post-marketing surveillance, and approval of drugs; and was involved in the drafting of those regulations.<sup>56</sup>

**1. FDA** -- Plaintiff's assertion that "Wyeth has specifically stated that it has no challenge to this testimony"<sup>57</sup> appears to be premature if I correctly read paragraph 1 of Defendant's response letter of July 28, 2006.<sup>58</sup> I hold, in general, that Dr. Gueriguian's testimony on the points in the letter regarding the FDA are admissible.<sup>59</sup> I reserve the right, of course, to exclude specific testimony at the trial. This means that Plaintiff must pare Dr. Gueriguian's testimony on this point, as well as others, to the essentials.

**2. Label/Warnings** -- I will permit Dr. Gueriguian to relate a brief history (assuming it is based upon adequate data). Distilling voluminous documents is proper. While it is true that jurors can read documents, the trial would last months if they were required to read every admissible document. Further, I will permit Dr. Gueriguian to testify how he thinks Wyeth should have responded, but not how they would have.

**3. History of Premarin and Prempro** -- a short history will be permitted. See the next preceding paragraph.

**4. Breast Cancer Signals** -- Dr. Gueriguian will be permitted to testify that the recognition of signals should (not would) have led to studies and different warnings.

---

<sup>56</sup>*Id.*

<sup>57</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), Doc. No. 289.

<sup>58</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), Doc. No. 297.

<sup>59</sup>See *In re Diet Drugs*, 2001 WL 454586, \*24 (E.D. Pa. Feb. 1, 2001) (holding that "(a) Dr. Gueriguian's expert testimony about the standard of care in the pharmaceutical industry regarding the manner in which certain information should be communicated to the FDA; and (b) what FDA officials would have done with certain additional information such as particular adverse event reports" was admissible).

**5. Cardiac Benefits** -- Since Ms. Reeves was prescribed HRT based on the alleged cardiac benefit, Dr. Gueriguan's testimony regarding this issue is relevant.

**6. Risk vs. Benefit** -- this will be permitted, in general. In other words, he can testify about the risk/benefit considerations with respect to prescription drugs in general as well as this particular drug.

**7. “New Prempro”** -- After reading Plaintiff's Supplemental Filing Re: Wyeth's Motion in Limine No. 16 to Exclude Reference to “Low Dose” Prempro<sup>60</sup> and considering argument heard during the August 15, 2006 hearing, I believe Dr. Gueriguan should be permitted to refer to “Low-Dose” Prempro. (Since the drafting of this order, Defendant has filed a new motion regarding “Low-Dose” Prempro. This motion will be dealt with later today or tomorrow.)

Incidentally, I note that in paragraph 7 of Defendant's letter of July 28 (re: The Scope of Dr. Gueriguan's Testimony) states, “that is why this is a failure to warn, not a design defect case.” I realize that this is Wyeth's position, but I have previously ruled that it is a design defect case too.

**8. Reasonable Drug Company** -- The last paragraph of Defendant's letter refers to Dr. Gueriguan's proposed testimony about “a reasonable drug company.” Arkansas Code Annotated § 16-116-104 provides:

(a)(1) In determining the liability of the manufacturer, the state of scientific and technological knowledge available to the manufacturer or supplier at the time the product was placed on the market, rather than at the time of the injury, may be considered as evidence.

---

<sup>60</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), Doc. No. 291.

(2) Consideration may also be given to the customary designs, methods, standards, and techniques of manufacturing, inspecting, and testing by other manufacturers or sellers of similar products.<sup>61</sup>

So, if Dr. Gueriguian has sufficient information, he can testify about the customs in the drug manufacturing world.

**E. Defendant's Motion to Exclude the Expert Testimony of Dr. David Sackett (Doc. No. 144)**

Dr. Sackett is prepared to testify that (1) Wyeth violated the principles of evidence-based medicine by failing to conduct a WHI-type study in the 1970s, and (2) that Wyeth intended to promote HRT for its potential cardiac benefits. Plaintiff contends that Dr. Sackett's testimony supports her negligence claim.<sup>62</sup>

Defendant contends that Dr. Sackett's testimony regarding the duty to perform a large, randomized study will be duplicative of Dr. Gueriguian's testimony. Defendant asserts that Dr. Sackett can't say what kind of study Wyeth should have conducted, and he doesn't follow a methodology, rely on any regulatory requirements, nor does he rely on any industry standards.<sup>63</sup>

Dr. Sackett is "a 40-year-veteran in the fields of internal medicine and clinical epidemiology, with particular interest in the principles and practices of evidence-based medicine."<sup>64</sup> He has also been the chair of several different randomized drug trials.<sup>65</sup> With these

---

<sup>61</sup>For a good summary of the law pertaining to "custom" see PROSSER AND KEETON ON THE LAW OF TORTS § 33 (5th Ed. 1984); *See also*, RESTATEMENT (THIRD) OF TORTS § 13 (2005).

<sup>62</sup>Doc. No. 213.

<sup>63</sup>*Reeves v. Wyeth*, 4:05-CV-00163 (E.D. Ark.), July 14, 2006 Tr. at 169-70.

<sup>64</sup>Doc. No. 213.

<sup>65</sup>*Id.*

credentials, he is clearly qualified to testify about evidence-based medicine and the necessity of large randomized clinical trials to determine the risks and benefits of drugs.

**1. Duplicity** -- Defendant's position on duplicity is not convincing. First Dr. Sackett suggests the study should have been done in the 1970s and Dr. Gueriguian says it should have been done in the 1980s. Second, Plaintiff claims that although the testimony of Dr. Sackett and Dr. Gueriguian overlap, they both have their specialties and their opinions must be viewed together. Third, Plaintiff contends that she does not intend to ask them the same questions. If the testimony is too duplicative, I will intervene and encourage leaner presentations.

**2. Type of Study** -- Contrary to Defendant's position that Dr. Sackett didn't explain what type of study should have been conducted, Dr. Sackett contends that a WHI-type study was necessary and would have put Defendant on notice regarding the alleged lack of cardiac benefits.<sup>66</sup> I agree with Defendant that Dr. Sackett's opinion regarding the specifics of the study is vague. However, it seems to me that Dr. Sackett's vagueness goes to the weight of his testimony rather than its admissibility.

**3. "Fit"** -- Defendant's argument regarding "fit" lacks merit. Because evidence regarding cardiac benefits is relevant to this case, Dr. Sackett's testimony regarding testing for a cardiac benefit is admissible.

Obviously, Dr. Sackett is not qualified to testify about FDA standards, but Plaintiff concedes that he's not going to talk about that. Nor will Dr. Sackett be permitted to testify as to what Wyeth should have or could have done to be a leader in the industry.

---

<sup>66</sup>*Id.*

**F. Plaintiff's Motion to Preclude Defendant's Experts from Testifying That There is No Reliable Scientific Evidence that Combination Hormone Therapy Can Cause Breast Cancer (Doc. No. 193)**

As with Defendant's objections to Plaintiff's causation experts, each argument appears to go to credibility, not admissibility, and can be raised on cross-examination.

**G. Defendant's Motion for Summary Judgment Re: Specific Causation (Doc. No. 87)**

Since Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation was denied, material facts remain in dispute as to causation.

### **CONCLUSION**

Based on the findings of fact and conclusions of law made during the hearings and above:

1. Defendant's Motion to Exclude Expert Testimony of Drs. Klimberg and Waldron as to Specific Causation (Doc. No. 136) is DENIED.
2. Defendant's Motion to Exclude Expert Testimony of Dr. Hollon (Doc. No. 140) is DENIED, except as to the limitations mentioned above.
3. Defendant's Motion to Exclude Testimony of Dr. Gueriguan (Doc. No. 142) is DENIED, except as to the limitations mentioned above.
4. Defendant's Motion to Exclude Expert Testimony of Dr. Sackett (Doc. No. 144) is GRANTED regarding testimony about FDA standards and what Defendant could do to be a leader in the industry. The motion is DENIED regarding the remaining points.
5. Defendant's Motion to Exclude Expert Testimony of Dr. Austin (Doc. No. 148) is GRANTED as it concerns testimony regarding causation and DENIED as to the remaining points.

6. Plaintiff's Motion to Preclude Defendant's Experts from Testifying That There is No Reliable Scientific Evidence that Combination Hormone Therapy Can Cause Breast Cancer (Doc. No. 193) is DENIED.

7. Defendant's Motion for Summary Judgment Re: Specific Causation (Doc. No. 87) is DENIED.

Most of the arguments regarding exclusions of experts overlapped with the issues in *Reeves v. Wyeth* -- as evidenced by the fact that Ms. Rush filed identical responses to the motions to exclude as Ms. Reeves. For that reason, in this case, I have considered the positions that were argued by Ms. Reeves's counsel in subsequent oral argument and letter exchanges. However, if there are any *Daubert* issues that are unique to Ms. Rush, which are not addressed in this order, the parties should file the appropriate motion no later than 5 p.m., Thursday September 21, 2006.

IT IS SO ORDERED this 13th day of September, 2006.

/s/ Wm. R.Wilson,Jr.  
UNITED STATES DISTRICT JUDGE